

## REMARKS

With this response, claims 37-39, 41-53, 61-64, and 73-77 are pending. Claims 1-36, 40, 54-60 and 65-72 were previously canceled without prejudice or disclaimer. Claims 61-64 and 73-76 have been withdrawn from further consideration as being drawn to non-elected inventions.

Claims 37, 45, 50 and 53 are amended herein. Support for these amendments can be found in the specification as filed. For example, the specification as filed describes recombinant expression and synthesis of the subject fusion proteins, as well as purification of same at page 9, lines 29-33 and at page 17, lines 1-18, respectively. Additionally, chimerism between the first and second domains of the fusion protein is depicted at Figure 1b and described at page 11, line 34 to page 12, line 2, *inter alia*. Accordingly, no new matter is entered by way of these amendments.

### **1. Rejections under 35 U.S.C. § 101**

Claims 37-39, 41-51, and 77 are rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. In particular, it is alleged that the claims, as written, do not sufficiently distinguish over the claimed polypeptide compounds as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed fusion proteins and naturally occurring fusion proteins. Without acquiescing to the allegation, and solely for the purpose of expediting prosecution, independent claim 37 has been amended to recite that the claimed fusion protein is “recombinant.” Additionally, claim 45 has been amended to recite that the claimed fusion protein is “purified.” Applicants respectfully assert that the claims as amended satisfy the requirements under 35 U.S.C. § 101 and, as such, respectfully request withdrawal of the rejections on this basis.

### **2. Rejections under 35 U.S.C. § 112**

#### **Claim 53**

Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, it is alleged that recitation of “the compound” in reference to the parental claim lacks sufficient antecedent basis in the parental claim. Without acquiescing to the allegation, and solely for the purpose of expediting prosecution, claim 53 has been amended to

delete recitation of “the compound” and to recite “the fusion protein.” Applicants respectfully assert that such recitation has antecedent basis, and respectfully request withdrawal of the rejections under 35 U.S.C § 112, second paragraph.

Claims 37 and 50

Claims 37 and 50 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, it is alleged that claim 50 is drawn to the fusion protein of claim 37, wherein the first binding domain comprises the peptide sequence of the c-myb DNA binding and claim 37 requires that the first binding domain bind to one molecule selected from the group consisting of AML 1-ETO, BCR-Abl, PML-RARalpha, PLZF-RARalpha, and EWS-FLI, and while the specification does not describe a c-myb DNA binding domain having the ability to bind said molecules. Without acquiescing to the allegation, and solely for the purpose of expediting prosecution, claim 50 has been amended to recite that the second binding domain that effects dyslocalization comprises the peptide sequence of the c-myb DNA binding domain.

**3. Rejections under 35 U.S.C. § 102**

Claims 37, 44, 45, and 47

Claims 37, 44, 45, and 47 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Coutinho et al. (Blood 2000: 96: 618-624) evidenced by McWhirter et al. (Mol. and Cell. Biol. 1993, 13: 7587-759, previously cited). Applicants respectfully disagree.

As described in the application as filed, the fusion protein comprises a first and second domain, wherein the first and second domains are chimeric, e.g., derived from two different proteins. An exemplary fusion protein as described comprises a first domain derived from myeloid elf-like factor (MEF) and a second domain derived from c-myb. *See, e.g., Specification*, at p. 11, line 34, to p. 12, line 2, and Figure 1b. The first and second domains of the instant fusion proteins binds one molecule selected from the group consisting of AML1-ETO, BCR-Abl, PML-RARalpha, PLZF-RARalpha, and EWS-FLI and effects dyslocalization of said molecule, respectively.

Applicants respectfully assert that the present claims are patentable over Coutinho since the cited reference does not teach, or even suggest, every element of the instant claims. *See, MPEP* § 2131 (stating “A claim is anticipated only if each and every element as set forth in the

claim is found, either expressly, or inherently described, in a single prior art reference.”) (citing *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628 (Fed. Cir. 1987)). Coutinho describes a fusion protein, Grb4-EYFP. According to Coutinho and the Examiner, the binding and dyslocalization of BCR-Abl by this fusion protein is solely effected by Grb4. *See, Coutinho*, at p. 623 (stating “Grb-4 . . . showed binding to Bcr-Abl via its SH3 domains. . . when coexpressed with WT [wildtype] Bcr-Abl, . . . Grb4 colocalized with WT Bcr-Abl and redistributed into punctate aggregates”); *see also Office Action*, at p. 4 (stating “binding of either domain of GRB4 contributes to the dyslocalization of BCR-Abl.”). Since the alleged binding and dyslocation of BCR-Abl is effected by a single protein, Coutinho cannot describe a fusion protein wherein the first domain that binds BCR-Abl and the second domain that effects its dyslocalization are chimeric, i.e., from two different proteins. Additionally, Coutinho does not suggest such a fusion protein. Since Coutinho fails to teach or suggest chimerism between the domains effecting binding and dyslocalization of the subject molecules, Coutinho does not anticipate or make obvious the present claims.

Having distinguished the independent claim from the art of record, claims dependent therefrom are patentable for at least the same reasons. However, Applicants reserve the right to separately address the patentability of those claims in the future, should that be necessary.

#### **4. Claim Objections**

##### **Claim 45**

Claim 45 is objected to as being in improper dependent form for allegedly failing to further limit the subject matter of the previous claim. Without acquiescing to the allegation, and solely for the purpose of expediting prosecution, claim 45 is amended herein to recite that the fusion protein is purified. Applicants respectfully assert that amendment of claim 45 renders the claim objection inapposite, and Applicants accordingly request withdrawal of the objection on this basis.

#### **CONCLUSION**

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the above amendment and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this

application in any way, the Examiner is invited to contact the undersigned by telephone at (202) 942-5000 or by fax at (202) 942-5999.

Respectfully submitted,

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